MAR 2 8 2005

K050623

Volk Optical, Inc.

510(k) SUMMARY OF SAFETY AND SUBSTANTIAL EQUIVALENCE

Date: March 7, 2005

Submitter:
Volk Optical, Inc.
7893 Enterprise Drive
Mentor, Ohio 44060
(440) 942-6161

Contact Person:

Michaeleen Dom

Official Correspondent:

Richard E. Lippman, O.D., F.A.A.O.
Vice President Ophthalmic Product Regulatory Affairs
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Road
Suite 30
Rockville, Maryland 20850
(240) 683-3738

Device Name:

Trade Name:	Volk Disposable Vitrectomy Lenses
Common Name:	Vitrectomy contact lens
Classification Name:	Lens, Contact- Diagnostic

Device Classification: 21 CFR 886.1385
Class II

Product Code: HJK

Device Description:

The subject device is a diagnostic and therapeutic contact lens system used for eye fundus examination and therapy of intraocular abnormalities. The lens is one element made from PMMA (polymethylmethracryalate). The lens is a sterile, disposable, single use device.

Intended Use:

The devices are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities. The devices are sterile, single use, disposable lens systems.

Substantial Equivalence:

The Volk Disposable Vitrectomy Lenses are substantially equivalent in design, material, classification, and intended use to vitrectomy lenses cleared for marketing by Ocular Instruments, Inc. (K012096), and Volk Optical, Inc. (K943125). See chart below.

Volk Optical, Inc.

Comparison	*Volk Contact & Laser Diagnostic Lenses (current application)*	*Volk Quadraspheric Fundus Lens (K943125)*	*Ocular Disposable Vitrectomy Lenses (K012096)*
Indication for Use	Diagnostic contact lens for eye fundus examinations and use in the therapy of intraocular abnormalities	Diagnostic contact lens for eye fundus examinations and use in the therapy of intraocular abnormalities	Visualizastion of the ocular fundus, vitreous and retinal structures during vitrectomy surgeries.
Design	Various designs include the flat, wide field and 30^0 prism.	Various designs include the flat, wide field and 30^0 prism.	Various designs include the flat, wide field and 30^0 prism.
Materials	PMMA	PMMA	PMMA
Sterility	EO Sterilized	Non-sterile	EO Sterilized

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Volk Optical, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
Official Correspondent for Volk Optical, Inc.
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Rd., Suite 30
Rockville, MD 20850

Re: K050623
Trade/Device Name: Volk Disposable Vitrectomy lenses
Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate (PMMA) diagnostic contact lens
Regulatory Class: Class II
Product Code: HJK
Dated: March 9, 2005
Received: March 10, 2005

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known) K050623

Device Name: Volk Disposable Vitrectomy Lenses

Indications for Use:

The devices are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities. The devices are sterile, single use, disposable lens systems.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, PH.D.

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K050623